

# CLASSIFICATION OF IVDS ACCORDING TO IVDR 2017/746

LOW PERSONAL RISK,  
LOW PUBLIC HEALTH RISK

CLASS  
**A**

Examples

- Accessories •
- Wash buffers •
- Specimen receptacles •
- Instruments •
- Culture media •



HIGH PERSONAL RISK,  
MODERATE TO LOW PUBLIC  
HEALTH RISK

CLASS  
**C**

Examples

- Syphilis (diagnosis only)
- Neonatal screening for metabolic disorders e.g. PKU
- Rubella
- Cancer markers (screening and diagnosis)
- Genetic tests
- Companion diagnostics
- Blood glucose meters/strips
- Blood gas analysers
- Self tests
- Cardiac markers
- Tissue typing e.g. HLA



MODERATE TO LOW  
PERSONAL RISK,  
LOW PUBLIC HEALTH RISK

CLASS  
**B**

Examples

- Thyroid, kidney, liver function tests •
- Infertility assays •
- Clinical chemistry •
- Hormones, enzymes, proteins •
- Inf ammatory markers •
- Rheumatology markers •
- Self-test devices •  
that are not Class C:  
pregnancy, fertility,  
cholesterol and  
urine tests for glucose,  
erythrocytes, leucocytes  
and bacteria



HIGH PUBLIC HEALTH RISK,  
HIGH PERSONAL RISK

CLASS  
**D**

Examples

- Blood donation screening e.g. Syphilis, CHAGAS, HTLV I/II
- Blood grouping ABO, Rhesus (including RHW1), Kell, Kidd and Duffy systems.
- Diagnostic test e.g. HIV 1/2

